



Region IX
Office of Audit Services
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Room 171
San Francisco, CA 94102

Report Number: A-09-02-01004

July 9, 2004

Ms. Laura L. LaCorte
Senior Associate Vice President
University of Southern California
Office of Compliance
3500 South Figueroa
University Gardens
Los Angeles, California 90089-8007

Dear Ms. LaCorte:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG) final report entitled "Audit of Health Resources and Services Administration Cooperative Agreement Number U69-HA-00040" for the period September 1, 1999 through July 13, 2001. A copy of the report will be forwarded to the HHS action official noted below for review and any actions deemed necessary.

Final determination as to actions taken on all matters reported will be made by the action official. We request that you respond to the action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

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Please refer to report number A-09-02-01004 in all correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "Lori A. Ahlstrand".

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosures – as stated

Page 2 – Ms. Laura LaCorte

Direct Reply to HHS Action Official:

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Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AUDIT OF HEALTH RESOURCES AND
SERVICES ADMINISTRATION
COOPERATIVE AGREEMENT
NUMBER U69-HA-00040**

**UNIVERSITY OF SOUTHERN
CALIFORNIA
LOS ANGELES, CALIFORNIA**



**July 2004
A-09-02-01004**

Office of Inspector General

<http://oig.hhs.gov>

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OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.



EXECUTIVE SUMMARY

BACKGROUND

In its efforts to address HIV/AIDS among racial and ethnic minority populations, the Health Resources and Services Administration (HRSA) in September 1999 committed about \$2.5 million of Congressional Black Caucus¹ Minority AIDS Initiative funding to enter into a cooperative agreement, which is similar to a grant, with the University of Southern California (USC) for a HIV/AIDS peer treatment educator training program (program) designed to:

- create an HIV/AIDS training center at USC
- develop an HIV/AIDS treatment and curriculum program for peer treatment educators
- establish mentor and internship programs for peer treatment educators
- evaluate the peer treatment training program
- replicate the peer training and curriculum nationwide

USC assigned a principal investigator (PI) and a co-PI to the program. Under USC policies, the PI is responsible for management, scientific, and technical direction of the program. To augment university staff on the program, USC also subcontracted with a nonprofit organization, African-American Aids Policy and Training Institute (subcontractor), to primarily perform programmatic and support functions for the program.

HRSA provided consultation and technical assistance to the program, including onsite visits to assess program activities. In July 2001, HRSA suspended the program after a diagnostic site visit disclosed serious problems regarding possible violations of Institutional Review Board (IRB) and human subject protections, conflict of interest, and misuse of Federal funds. At that time, HRSA requested the Office of Inspector General to conduct an audit of the program.

OBJECTIVE

Our overall objective was to determine if USC adequately managed program activities and funds. To accomplish this, we determined whether USC:

- met program objectives
- adhered to the IRB conditions
- managed the program free of a conflict of interest
- appropriately claimed costs

¹ Founded in 1971 by African-American members of the U.S. House of Representatives, the Congressional Black Caucus addresses legislative concerns of African-Americans and other minority citizens.

SUMMARY OF FINDINGS

We have concerns about the manner in which USC managed the program activities and funds.

- **USC did not meet the program’s objectives.** It did not implement an effective training program for HIV/AIDS peer treatment educators to provide treatment education to individuals infected with HIV, establish mentor and internship programs, or evaluate the program. The objectives were not accomplished primarily because USC used inexperienced personnel to implement critical aspects of the program.
- **USC conducted research involving human subjects without proper authorization.** Specifically, the program proceeded with research involving human subjects—the peer treatment educators, many of whom were HIV positive—without the approval of USC’s IRB. This approval was required by Federal regulations at 45 CFR part 46 to protect the rights of human subjects. Program activities proceeded without IRB approval because the program’s co-PI did not agree with the IRB’s conclusion that the program was conducting research involving human subjects.
- **USC did not resolve a conflict of interest situation where the program’s co-PI also held a management position with the subcontractor.** Such a conflict is contrary to code of conduct provisions at 45 CFR part 74.42. This conflict continued throughout the program period because USC did not follow through to rectify the problem.
- **USC improperly claimed a majority of program costs.** Of the \$1,266,882² that USC incurred for the program, we recommended disallowance of \$1,082,554 (about 85 percent) because the costs were not allowable, allocable, or reasonable, as required by Federal cost principles at 45 CFR part 74. Our recommended disallowance included unallowable costs, costs related to unapproved research involving human subjects, and certain funds expended without HRSA’s prior approval. There is an additional \$41,587 in costs that we have set aside for HRSA to determine allowability.

These findings led us to conclude that USC did not adequately manage the program activities and funds. As a result:

- Federal funds totaling about \$1.2 million were expended for a program that did not meet its overall objective: to establish a nationwide network of individuals who can provide HIV/AIDS treatment education to racial and ethnic minorities and train other peer treatment educators.

² Out of the \$1,266,882 in expenditures charged to the cooperative agreement, \$64,833 was still pending reimbursement by the Federal Government, due to HRSA's suspension of the program.

- There was no assurance that there was adequate protection for the rights and welfare of the program’s human subjects—the peer treatment educators—many of whom were HIV positive.
- There was no assurance that Federal interests were protected while a conflict of interest persisted.
- Congressional Black Caucus Minority AIDS Initiative funding devoted to this program was not used productively to address the challenges of HIV/AIDS among racial and ethnic minority populations. About 85 percent of the total costs incurred did not meet Federal cost principles, comply with IRB restrictions, or have HRSA’s prior approval.

RECOMMENDATIONS

We recommend that USC:

1. strengthen its cooperative agreement implementation process to include the full support of the university community by ensuring that the proper organizational infrastructure and managerial, professional, and research expertise are available for meeting the objectives of future federally funded programs
2. establish independent oversight of investigators who need increased supervision
3. ensure that university offices involved in the approval of and funding for research activities work together to clarify guidelines and improve communications related to programmatic decisions and funding actions
4. strengthen procedures for reviewing, identifying, and resolving potential and actual conflicts of interest
5. refund to HRSA \$1,024,308 in unallowable costs that have been reimbursed, and exclude \$58,246 in unallowable costs pending Federal reimbursement (the unallowable reimbursed and unreimbursed costs total \$1,082,554)
6. work with HRSA to resolve the allowability of \$41,587 in costs (\$35,221 reimbursed and \$6,366 unreimbursed) that we set aside

USC COMMENTS

In written response to the draft report, USC concurred with the procedural recommendations, numbered 1 through 4 above, and also concurred with recommendation 6. USC did not concur with recommendation 5, related to unallowable costs. In its response, USC asserted that we should have relied on a comprehensive audit by PricewaterhouseCoopers of the costs incurred by USC’s subcontractor. USC also stated that HRSA retroactively approved some costs and that there was not enough

information in our report for USC to understand the basis for many of the recommended disallowances.

The complete text of USC's written response is included in its entirety as an appendix to this report.

OFFICE OF INSPECTOR GENERAL RESPONSE

We do not agree with USC's comments pertaining to recommendation 5. We reviewed the PricewaterhouseCoopers report and determined that it was not an audit and, therefore, we could not rely upon it. Correspondence provided to us on this project did not show that HRSA granted retroactive approval for any costs that we recommended for disallowance. Additionally, our report contains sufficient information to explain the reasons for the recommended disallowances. If requested by HRSA officials, we will make audit documentation available to assist them in resolving the audit findings.

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U69-HA-00040

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C - USC'S WRITTEN RESPONSE TO AUDIT FINDINGS AND RECOMMENDATIONS

INTRODUCTION

BACKGROUND

HRSA Established Program With Minority AIDS Initiative Funding

In September 1999, HRSA awarded a sole-source cooperative agreement³ to the USC AIDS Social Policy Archive to implement a program for HIV/AIDS peer treatment educator training. The program, part of the Congressional Black Caucus Minority AIDS Initiative, was considered a pivotal part of HRSA's response to address HIV/AIDS among racial and ethnic minority populations. It was designed to train, place, and support a cadre of HIV/AIDS peer treatment educators to provide counseling and treatment education in their respective communities.

The objectives of the program were to (1) create a HIV/AIDS training center at USC, (2) develop an HIV/AIDS treatment training and curriculum program for peer treatment educators, (3) establish mentor and internship programs for the peer treatment educators, (4) evaluate the peer treatment program based upon data collected, and (5) replicate the training and curriculum nationwide. As a part of the cooperative agreement, HRSA made onsite visits to assess program activities, and provided technical assistance.

The cooperative agreement was slated to cover the period September 1, 1999 through March 29, 2002, with total funding planned for \$2,525,000. Because HRSA restricted the drawdown of Federal funds on April 11, 2001, and subsequently suspended the cooperative agreement on July 13, 2001, only \$1,266,882 was actually expended.

Cooperative Agreement Awarded to USC's AIDS Social Policy Archive

USC, a private nonprofit educational institution founded in 1880, had various organizational components involved in the program's activities, including the AIDS Social Policy Archive located within the Information Services Division, the Department of Contracts and Grants (grants office), and the IRB.

- USC's AIDS Social Policy Archive received the award. Part of the Information Services Division's Specialized Libraries and Archival Collections (formerly known as the Special Collections), this archive houses the various papers of AIDS activists and elected officials who pioneered AIDS policies for the City of Los Angeles. The Information Services Division is responsible for serving the USC

³ A cooperative agreement is an alternative instrument used in lieu of a grant whenever substantial Federal involvement is anticipated. The difference between a cooperative agreement and a grant is the degree of Federal programmatic involvement rather than the type of administrative requirement imposed. Unless specifically excluded by the agreement, laws, regulations, and policies that are applicable to grants also apply to cooperative agreements.

community's needs, which include computer networking, library services, academic computing, and telecommunications.

- The grants office is charged with assuring that USC complies with both sponsor and university requirements. This office administered the HRSA award, distributed the internal notification of award, and prepared subcontracts for the program.
- The University Park IRB is responsible for reviewing all research proposals made by this campus's faculty, staff, and students that involve the use of human subjects.

USC policies provided that proposals for external support be submitted by a member of the university faculty who will personally participate in the sponsored project as the PI. The PI is the individual responsible for (1) the management of the project, (2) the project's scientific, technical, and fiscal direction, and (3) observance of all of the policies and procedures required by USC and the project sponsor.

Program Positions

The USC positions⁴ and program duties funded by the award included:

<u>USC Position</u>	<u>Duties</u>
Director (the co-PI)	meet program obligations, supervise program staff, maintain strategic research relations including liaison with the IRB, and advise on curriculum development
Project Manager	design and develop program training protocols, develop curriculum, and analyze and evaluate the program
Assistant	assist with developing curriculum, distributing marketing materials, and selecting peer treatment educators
Training Specialist	develop and implement outreach strategies to recruit peer treatment educators, mentors, and AIDS service organizations to participate in the program
Administrative Services Manager	manage administrative and financial operations of the training center

USC Subcontracted for Program Assistance

USC subcontracted a portion of the work, mostly programmatic and support functions, to a nonprofit public benefit corporation. The nonprofit corporation was formed in May 1999, 4 months before the HRSA award to USC. As defined in its bylaws, the

⁴ The individuals hired by USC for these USC positions were current/former employees or consultants of the subcontractor.

subcontractor's purpose was to (1) conduct policy development and training activities designed to reduce the rate of new HIV infections in African-American populations, (2) assist African-Americans living with HIV in deriving the maximum benefit from currently available and developing therapies and interventions, and (3) conduct research and publishing activities designed to support its development and training activities. The sole founder of the nonprofit organization, who was the program's co-PI, was hired by USC in January 2000.

The subcontractor's scope of work for the program, as defined in the USC subcontract, included providing office and training space, equipment, salary support for internships, mentors, and a monthly newsletter and Web site for the peer treatment educators. The subcontractor's period of performance was September 1, 1999 through March 21, 2001.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

In July 2001, HRSA requested an audit of the cooperative agreement, citing concerns regarding possible violations of IRB and human subject protections, conflict of interest, and misuse of Federal funds. Our overall objective was to determine if USC adequately managed program activities and funds. To accomplish this objective, we determined whether USC:

- met program objectives
- adhered to the IRB conditions
- managed the program free of a conflict of interest
- appropriately claimed costs

Scope

The period of our review was September 1, 1999 through July 13, 2001. We limited our review of internal controls to obtaining an understanding of USC's policies and procedures regarding conflict of interest, sponsored programs, research involving human subjects, and the recording and reporting of costs incurred under the award.

Methodology

To accomplish our objective, we reviewed applicable Federal regulations, HRSA's justification for a sole source award to USC, the notice of award, application and terms and conditions of the cooperative agreement, applicable USC policies and procedures, program reports, and documentation maintained by the grants office and the IRB. Further, we obtained an understanding of program administration through discussions with various USC officials, and examined supporting documentation, such as accounting records, invoices, contracts, and consulting agreements applicable to the costs claimed by both USC and the subcontractor.

The costs considered incurred and charged to the HRSA award were the program costs recorded to USC's accounting records as of November 14, 2002. As of that date, USC's accounting records for the program showed that USC had incurred and charged \$1,266,882 to the HRSA award. However, not all of these expenditures had been reimbursed by the Federal Government due to the suspension of the program by HRSA. Based on information provided by USC, expenditures totaling \$64,833 were still pending Federal reimbursement.

For the subcontractor's costs charged to the program by USC, we reviewed supporting documentation at the subcontractor to determine if the costs were allowable, allocable, and reasonable. The subcontractor costs charged to the program, were the costs invoiced to USC totaling \$500,898 and recorded in USC's accounting records.

Because the subcontractor occasionally invoiced costs based upon its approved budget and/or estimates, we were not always able to reconcile the costs invoiced to the subcontractor's general ledgers. In those circumstances, subcontractor officials identified the general ledger transactions that comprised the cost categories invoiced.

We conducted our audit in accordance with generally accepted government auditing standards. We performed our fieldwork, which included visits to USC and the subcontractor in Los Angeles, from February 2002 through September 2003.

FINDINGS AND RECOMMENDATIONS

We have concerns about the manner in which USC managed the program activities and funds.

- **USC did not meet the program's objectives.** It did not implement an effective training program for HIV/AIDS peer treatment educators to provide treatment education to individuals infected with HIV, establish mentor and internship programs, or evaluate the program. The objectives were not accomplished primarily because USC used inexperienced personnel to implement critical aspects of the program.
- **USC conducted research involving human subjects without proper authorization.** Specifically, the program proceeded with research involving human subjects—the peer treatment educators, many of whom were HIV positive—without the approval of USC's IRB. This approval was required by Federal regulations at 45 CFR part 46 to protect the rights of human subjects. Program activities proceeded without IRB approval because the program's co-PI did not agree with the IRB's conclusion that the program was conducting research involving human subjects.
- **USC did not resolve a conflict of interest situation where the program's co-PI also held a management position with the subcontractor.** Such a conflict is contrary to code of conduct provisions at 45 CFR part 74.42. This conflict

continued throughout the program period because USC had not followed through to rectify the problem.

- **USC improperly claimed a majority of program costs.** Of the \$1,266,882 that USC incurred for the program, we recommended disallowance of \$1,082,554 (about 85 percent) because the costs were not allowable, allocable, or reasonable, as required by Federal cost principles at 45 CFR part 74. Our recommended disallowance included unallowable costs, costs related to unapproved research involving human subjects, and certain funds expended without HRSA's prior approval. There is an additional \$41,587 in costs that we have set aside for HRSA to determine allowability.

These findings led us to conclude that USC did not adequately manage the program activities and funds. As a result:

- Federal funds totaling about \$1.2 million were expended for a program that did not meet its overall objective: to establish a nationwide network of individuals who can provide HIV/AIDS treatment education to racial and ethnic minorities and train other peer treatment educators.
- There was no assurance that the rights and welfare of the program's human subjects—the peer treatment educators, many of whom were HIV positive—were adequately protected.
- There was no assurance that Federal interests were protected while a conflict of interest persisted.
- Congressional Black Caucus Minority AIDS Initiative funding devoted to this program was not used productively to address the challenges of HIV/AIDS among racial and ethnic minority populations. A significant amount of costs claimed for the program were unallowable, including costs that did not meet Federal cost principles, comply with IRB restrictions, or have HRSA's prior approval.

PROGRAM OBJECTIVES NOT MET

Even though the program operated for 23 of the 31 months of the HRSA-funded period, its activities were either not on target to meet the grant objectives or not performed at all. This situation resulted in Federal funds totaling about \$1.2 million being expended but not advancing HRSA's mandate to address HIV/AIDS among racial and ethnic minority populations. USC did not meet its objectives to develop the curriculum for peer treatment educators to provide treatment education to individuals infected with HIV and to train other treatment educators, establish mentor and internship programs, or evaluate the effectiveness of the training. The primary reason these objectives were not met was that USC assigned inexperienced personnel to the program.

USC Was Responsible for Achieving Program Objectives

The Federal regulation (45 CFR 74.51) governing awards to universities provides that grant recipients are responsible for managing and monitoring each program, subaward, function, or activity that is supported by the award. In addition, the Public Health Service Grants Policy, which is applicable to HRSA awards, provides that grantees employ sound management practices to ensure that program objectives are met.

Program Objectives Were Not Met

USC was not successful in implementing a program designed to strengthen HIV/AIDS treatment education for racial and ethnic minority populations, as follows:

- USC did not effectively carry out its responsibility to train 88 peer treatment educators. The program made limited progress in enrolling and providing training to 41 of the 50 expected first-year program participants, but there were problems with the training, as noted below. Further, the program did not meet its expectation to train an additional 38 individuals in the second year. An onsite HRSA diagnostic team visit, completed on June 1, 2001, identified several problems as to how the program provided training to the 41 participants.
 - **Unclear goals** – For example, it was not clear whether the peer treatment educators were to be trained as “advocates” or “treatment educators,” with the latter being especially problematic because of the time and instruction that participants would need to learn training methods and become knowledgeable about HIV/AIDS medical issues.
 - **Illogical training sequence** – There did not appear to be a logical sequence as to how the materials were organized or the order in which certain topics were presented.
 - **Incomplete documentation** – Regarding the course contents, the lack of documentation made it difficult to assess whether the training was appropriate for the participants.
- USC did not develop a replicable training curriculum that could be used by the peer treatment educators to train others. Although we requested the curriculum created for the program, USC was not able to provide one for our review. However, we did identify references to a curriculum in reports made by USC, HRSA, and a HRSA technical consultant. The comments generally indicated that the curriculum was neither well designed nor appropriate for many of the students in the program. In a September 2000 progress report, USC stated that the program had not obtained a replicable curriculum. We noted in this program’s proposal and HRSA’s guidelines that an objective of this cooperative agreement was to develop a replicable curriculum.

- USC did not establish a mentor or internship program. We found no evidence that a mentor program was established. A program official also confirmed that a mentor program had not been established. As for the internship program, there was also no evidence that the program had established internships for its participants.
- USC did not evaluate the training program. Although USC had collected data from the 41 peer treatment educators, an evaluation of the data was not completed because the IRB halted the program's activities in March 2001 since the program did not have the required IRB approval. (See "Research Involving Human Subjects" section.)

USC Assigned Inexperienced Personnel to the Program

The program did not accomplish its objectives primarily because USC assigned inexperienced personnel for critical aspects of its implementation. The university's organizational staffing and placement of the program within the Information Services Division adversely affected the program as described below.

- USC assigned a faculty member as the PI, as required by the university's policies for externally funded projects, but this individual, an Associate University Librarian, never participated in the program. Even if he had participated, the PI did not have a background in or experience with HIV training programs. In addition, USC's placement of the program within the AIDS Social Policy Archive, a special documents section maintained by the Information Services Division, did not ensure the professional expertise necessary to support and carry out the program. The problem with this organizational placement became apparent a year after the program began, when the Information Services Division acknowledged in an internal memorandum to the USC Vice Provost for Research that the training of HIV/AIDS peer treatment educators did not seem to fall within the boundaries of the division's expertise. We noted that USC attempted to relocate the program within another department; however, this did not occur before HRSA suspended the grant.
- USC assigned a co-PI, who ultimately ran the project, who was neither an experienced researcher nor a USC faculty member. As disclosed by the HRSA diagnostic team, in the research model used by USC to implement the program, PIs are expected to have established themselves in their areas of expertise and possess the knowledge and credentials to successfully carry out the terms of their grants. Because the co-PI was inexperienced in research and did not have faculty status at USC, he had limited knowledge of the research and training support systems available within the university setting—valuable resources that could have increased the program's chances for success. For example, USC has curriculum review committees and an AIDS education and training center, but the program did not avail itself of these potentially useful resources.

- USC hired personnel for the program who were not experienced in research and curriculum development. Program personnel had experience in AIDS service organizations and AIDS advocacy positions; however, based upon their resumes, they did not possess the necessary education and experience to perform research and develop a comprehensive curriculum for a 2-year training program, as required by the cooperative agreement.

The Federal Expenditures Did Not Produce a Network of Peer Treatment Educators

Federal expenditures totaling about \$1.2 million for the 2-year training program did not result in a nationwide network of knowledgeable individuals who could provide HIV/AIDS treatment education to racial and ethnic minorities and train others to provide such education. Even more critical, because the program did not meet its objectives over the grant period, it could not fulfill the long-term goal to have each of the initial participants train others who could then educate members of their communities. This goal included bringing 2,500 racial and ethnic minorities with HIV/AIDS into care and training an additional 1,000 peer treatment educators.

Recommendation

We recommend that USC:

1. strengthen its cooperative agreement implementation process to include the full support of the university community by ensuring that the proper organizational infrastructure and managerial, professional, and research expertise are available for meeting the objectives of future federally funded programs

USC Comments

USC concurred with the recommendation. In its written response, USC identified various steps it has taken to address this recommendation, including:

- revising its proposal approval record to address issues stemming from the cooperative agreement with HRSA
- developing a research audit compliance tool that (1) assists USC in determining which resources are required at the school and unit levels for meeting the requirements of the research sponsors, and (2) serves an educational function by reminding audited departments and units of the resources available to assist them

RESEARCH INVOLVING HUMAN SUBJECTS

The program conducted research involving human subjects—peer treatment educators, many of whom were HIV positive—without USC’s IRB approval and inappropriately used Federal funds for such research. The program contacted, recruited, and enrolled peer treatment educators into the research study, and collected data from them over the

course of the training for purposes of evaluation. Activities proceeded without IRB approval because the program's co-PI, who was not an experienced researcher, did not agree with the IRB's conclusion that the program involved research with human subjects. Since the research activities continued without the necessary approval, there was no assurance that the rights and welfare of the program's human subjects were adequately protected. Exacerbating the situation, USC's grants office, possibly due to a miscommunication, made all funds available to the program, even though the IRB had not approved the research activities.

Federal Regulations Require IRB Approval for Research Involving Human Subjects

Federal regulations for the protection of human subjects in research are contained in 45 CFR part 46. Within these regulations, section 46.109(a) requires that the entity's IRB review and have authority to approve or disapprove all research activities. Section 46.117 of these regulations provides that informed consent shall be documented by a written consent form approved by the IRB. The purpose of these regulations is to ensure that the rights and welfare of research subjects are protected. Additionally, section 46.122 prohibits an entity from spending Federal funds for research involving human subjects unless the IRB approves the research. To comply with this requirement, USC established a control whereby the grants office releases Federal funds for sponsored programs only after the IRB has provided written approval of research activities.

Program Conducted Research Without IRB Approval

Contrary to Federal regulations, USC's program conducted research involving human subjects—the peer treatment educators, many of whom were HIV positive—without IRB approval. Some of the program's activities were deemed to need IRB approval because they involved collecting and analyzing data from research subjects before, during, and after their training. The IRB identified the program as involving training and research; it granted approval for the administrative activities of setting up the training program, but did not approve the research. In terms of consent, which is required by Federal regulations, the peer treatment educators signed consent forms to participate in the research, but the form itself had not been approved as required by the IRB.

Although USC had procedures to prevent the release of Federal funds for research that had not received IRB approval, the procedures were not followed, and such funds were used to conduct unapproved research.

In May 2002, USC's IRB provided written notification to the Office for Human Research Protections (Agency) that research had occurred without IRB approval, and that the program had used unapproved consent forms in obtaining consent from the human subjects. Further, USC informed the Agency that the university was attempting to resolve this matter. This process, as of the end of our fieldwork, had not yet been fully completed since a final status report to the Agency was still pending.

The IRB’s Decision to Restrict Research Was Not Followed

The program conducted unapproved research involving human subjects and used Federal funds for such research because:

- The co-PI—not a member of the USC faculty nor a researcher, and who ran the project primarily unsupervised by the PI—did not agree with the IRB decision that the program involved research with human subjects. Thus, the co-PI proceeded to contact, recruit, enroll, test, and gather information from the peer treatment educators. In placing restrictions on the program’s activities, the IRB was concerned that research involved a vulnerable population—the peer treatment educators—who would be asked sensitive questions about their HIV status, sexual behaviors, and sexual orientation.
- USC’s administrative process in its grants office did not—as it was designed to do—prevent the expenditure of program funds related to research that had not received IRB approval. This deviation may have occurred because of a possible miscommunication in which the IRB notified the grants office of the restriction—to fund the administrative activities of setting up the training program, but not to conduct research—with a form the IRB normally uses when approving research. The grants office did not implement the research restriction indicated by the IRB in the text of the approval form.

Protection of Human Subjects Was Not Assured

Because research involving human subjects was conducted without IRB approval, there was no assurance that the rights and welfare of the minority peer treatment educators were adequately protected. Additionally, Federal funds were inappropriately used for this unapproved research. (See “Unallowable Costs Claimed” section.)

Recommendations

We recommend that USC:

2. establish independent oversight of investigators who need increased supervision
3. ensure that USC offices involved in the approval and funding for research activities work together to clarify guidelines and improve communications of decisions and funding actions to ensure compliance with Federal regulations

USC Comments

USC concurred with the recommendations. In its written response, USC identified various corrective actions it has implemented, including:

- developing a research compliance methodology to assist in identifying investigators or departments that may require additional oversight
- hiring an executive director for the newly created USC Office for Protection of Research Subjects, whose responsibilities include overseeing the operations of USC's IRBs and educating investigators and research staff about human subject protection issues
- establishing a number of formal and informal educational programs for investigators and staff
- expanding and formalizing internal Department of Contracts and Grants procedures to confirm that IRB approval must be obtained before investigators conducting research involving human subjects can obtain access to their funds
- formalizing a process to improve communications between the Department of Contracts and Grants and the IRB

CONFLICT OF INTEREST

USC did not resolve a conflict of interest—that the program's co-PI was at the same time a USC employee hired specifically for the program and the chief executive officer of the subcontractor—even though HRSA had raised concerns about the conflict early in the program period. Federal regulations prohibit grant employees who have real or apparent conflicts of interest from participating in the selection, award, or administration of a Federally supported contract. USC had not followed through with its oversight responsibility to rectify such a conflict. Because a conflict of interest existed in the expenditure of Federal funds, as in the case of this USC program, there was no assurance that Federal interests were adequately protected.

Federal Regulations Prohibit Conflicts of Interest

Federal regulation 45 CFR part 74.42, which sets forth administrative requirements for awards to universities, requires that no employee shall participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest exists.

Program Had a Conflict of Interest and USC Did Not Take Adequate Steps to Resolve It

USC did not follow Federal regulations regarding conflicts of interest and did not take adequate steps to ensure the conflict was resolved. Responding to HRSA's concern expressed in March 2000 about the co-PI's dual role, the co-PI appeared to have relinquished his managerial responsibilities within the subcontractor's organization in October 2000 by resigning as president, chief executive officer, and executive director to become chairman of the board. Such a change appeared to be in name only.

Analysis of the subcontractor's bylaws revealed that the chairman of the board is to serve as chief executive officer in the absence of a president, thus leaving open an opportunity for the co-PI to continue in his managerial role. We concluded that the co-PI continued throughout the program period to perform management functions for the subcontractor, such as cosigning checks, approving check requests, supervising staff, and identifying himself as the executive director in internal documents.

USC, which was responsible for ensuring that Federal regulations were followed in carrying out this program, did not ensure that the co-PI had, as he agreed to do, resigned from the subcontractor's management structure.

No Assurance Federal Interests Adequately Protected

Because the co-PI represented both USC and the subcontractor, there was no assurance that Federal interests were adequately protected. Such conflicts may result in incentives that are not in the best interest of the Federal Government. In fact, we believe the co-PI's conflict led to program funds being spent on subcontractor activities that were unrelated to the training program. These activities included developing a proposal for future subcontractor work, soliciting sponsors for an AIDS march, and conducting townhall meetings in various States in conjunction with political action involving HIV issues. While these activities may have focused on HIV issues, they were not related to the HRSA award for the HIV/AIDS peer treatment educator training program.

Recommendation

We recommend that USC:

4. evaluate and strengthen its procedures for identifying, reviewing, and resolving potential and actual conflicts of interests

USC Comments

USC concurred with the recommendation and identified various actions taken or planned, including:

- revising its conflict of interest policies relating to research and general university business practices
- revising the conflict of interest statement in its proposal approval record to incorporate additional information to assist investigators in identifying whether they have an actual or perceived conflict of interest that requires disclosure
- addressing conflict of interest in research in great detail in USC's grant management education program, which became mandatory on July 1, 2004, for all PIs, co-PIs, and research administrators listed on a proposal approval record.

UNALLOWABLE COSTS CLAIMED

Of the \$1,266,882 of program costs incurred by USC for this program, \$1,082,554, or 85 percent, was not allowable; and \$41,587 was set aside for HRSA's determination of allowability. Federal requirements provide specific instructions as to the allowability of costs charged to Federal awards. The disallowances in this program occurred because USC did not adequately manage and oversee the expenditures of this Federal award. As a result, Congressional Black Caucus Minority AIDS Initiative Funding was not used appropriately to address HIV/AIDS among racial and ethnic minority populations.

Cost Claims Must Meet Federal Requirements

The Federal requirements applicable to the USC cooperative agreement are:

- 45 CFR Part 74 – Uniform Administrative Requirements for Institutions of Higher Education and Other Nonprofit Organizations
- 45 CFR Part 46.122 – Use of Federal Funds
- Office of Management and Budget (OMB) Circular A-21 – Cost Principles for Educational Institutions
- OMB Circular A-122 – Cost Principles for Nonprofit Organizations
- Public Health Services Grants Policy

We also applied the terms and conditions of the HRSA award and the contractual agreement between USC and the subcontractor in determining the allowability of costs claimed.

Consistent with the criteria cited above, costs are reimbursable under a Federal award if they:

- are reasonable, allowable, and allocable for the performance of the award
- conform to any limitations or exclusions set forth in the cost principles or in the award as to types or amounts of cost items
- are adequately documented

About \$1.1 Million in USC Costs Claimed Did Not Meet Federal Requirements

Of the \$1,266,882 of program costs incurred by USC, \$1,082,554, or 85 percent, was not allowable, and \$41,587 was set aside for HRSA's determination of allowability.

The details of the costs claimed, recommended for disallowance, and set aside for HRSA determination are shown in Appendices A and B of this report. Some of the costs

recommended for disallowance had more than one reason associated with their disallowance. Appendix A shows the total of all costs charged to the program. Appendix B details the subcontractor costs invoiced to USC.

Unallowable Costs

The \$1,082,554⁵ of costs recommended for disallowance represented the following:

- \$856,369 was not in accordance with Federal cost principles. For example, we identified personnel costs lacking required after-the-fact certifications, expenditures without supporting documentation, consultant services not related to the program, and associated indirect costs.
- \$203,393 was not in compliance with the IRB restrictions. These costs covered research activities that had not been approved by the IRB.
- \$22,792 did not have HRSA's prior approval. For example, travel costs were charged that did not have the required prior approval.

Costs Set Aside

The \$41,587⁶ set-aside represents costs for which we could not determine allowability. Some of the subcontractor's costs required allocation among benefiting programs, and other costs needed documentation that USC had not provided.

Lapse in Oversight Affected Financial Management

Although USC had systems and controls to manage Federal funds, this program, as illustrated by the three previously discussed findings, appeared to operate outside of these established checks and balances. Specifically, the program did not have sufficiently experienced personnel, the program conducted unapproved research, and the co-PI had a conflict of interest. These circumstances led to inappropriate program expenditures. Normally, the PI is responsible for ensuring that expenditures of Federal grant funds are appropriately made. With this program, however, the PI was inactive, leaving the co-PI, who had a conflict of interest, to essentially run the program without adequate oversight.

In addition, the subcontractor, who claimed costs totaling \$500,898, or about 40 percent of the total costs incurred, did not have adequate internal controls for managing a Federal project. This organization was established only 4 months before the award of the program.

⁵ The recommended disallowance consists of \$1,024,308 in costs that have been reimbursed and \$58,246 in costs that are pending Federal reimbursement.

⁶ The set-aside amount consists of \$35,221 in costs that have been reimbursed and \$6,366 in costs that are pending Federal reimbursement.

Program Expenditures Were Not Productive

Congressional Black Caucus Minority AIDS Initiative funding devoted to this program was not used productively to address the challenges of HIV/AIDS among racial and ethnic minority populations. In light of the budget constraints facing all levels of government in the area of HIV/AIDS treatment, the Federal funds expended on this project could have been put to better use by HRSA, who is responsible for providing a Federal safety net for persons living with HIV and AIDS.

Recommendations

We recommend that USC:

5. refund to HRSA \$1,024,308 in unallowable costs that have been reimbursed, and exclude \$58,246 in unallowable costs pending Federal reimbursement (the unallowable reimbursed and unreimbursed costs total \$1,082,554)
6. work with HRSA to resolve the allowability of \$41,587 (\$35,221 reimbursed and \$6,366 unreimbursed) in costs set aside

USC Comments

USC did not concur with our recommendation to refund \$1,082,554 in unallowable reimbursed and unreimbursed costs, but did agree to work with HRSA to resolve the allowability of \$41,587 in costs set aside.

Although USC acknowledged that mistakes were made on this project, it requested an opportunity to discuss the unallowable costs with HRSA for the following reasons:

1. The firm of PricewaterhouseCoopers conducted a comprehensive 6-month audit of the subcontractor, and its report is a more accurate reflection of allowable subcontractor costs than the Office of Inspector General's report. While USC agreed that certain costs are unallowable, USC provided several reasons for not considering the Office of Inspector General review of the subcontractor costs:
 - The Office of Inspector General onsite review at the subcontractor lasted less than 2 days.
 - PricewaterhouseCoopers had access to records and personnel, such as the subcontractor's accountant, that were not available to the Office of Inspector General.
 - The Office of Inspector General discounted the PricewaterhouseCoopers report in its entirety because it included costs charged by the subcontractor but not yet paid by USC.
2. Certain costs questioned by the Office of Inspector General had HRSA's retroactive approval; therefore, it was unreasonable to disallow those costs.

3. The Office of Inspector General’s rationale for disallowing certain costs for “unapproved research” involving human subjects was unclear. USC was addressing this matter when the project was suspended. In addition, an attempt was made to obtain written informed consent from the human subjects even if the consent document and the process for obtaining consent were not approved by the IRB.
4. There was insufficient information as to how the Office of Inspector General made its disallowance determinations and calculations. USC also stated that HRSA was actively involved with the project and was aware of certain expenses associated with the project.

The complete text of USC’s written response is included in its entirety as Appendix C.

Office of Inspector General Response

To accomplish our audit objectives, our policy is to make use of others’ work. We analyzed the PricewaterhouseCoopers report to determine if we could rely on it and determined that we could not.

- PricewaterhouseCoopers conducted an agreed-upon procedures engagement in accordance with Statements on Standards for Consulting Services of the American Institute of Certified Public Accountants. PricewaterhouseCoopers made no representation regarding the sufficiency of the procedures it used and expressed no opinion on the expenditures claimed under the subcontract. The report stated that it was not an audit of the subcontractor costs and that other matters might have come to the attention of PricewaterhouseCoopers if it had conducted additional procedures for purposes of expressing an opinion on the expenditures claimed by the subcontractor.
- The working papers provided to us consisted of only the report by PricewaterhouseCoopers and a related schedule. The schedule showed unallowable and unsupported costs totaling about \$28,775, and over \$200,000 in costs requiring further review. In our audit, we were able to determine the allowability of over 90 percent of the subcontractor costs claimed. We set aside the remaining balance for HRSA determination.
- Our onsite review at the subcontractor lasted longer than 2 days. In addition to our initial onsite visit, we returned later to continue the review. The subsequent review lasted approximately 16 business days.

USC expressed concerns about the lack of availability of subcontractor records and personnel, retroactive approval provided by HRSA, our rationale for disallowing certain costs for “unapproved research” involving human subjects, and insufficient information in the report for ascertaining how we calculated disallowances.

- We had sufficient access to subcontractor records and personnel to complete our review. We reviewed subcontractor documentation, such as general ledgers, invoices, personnel files, and e-mails. Current and former subcontractor personnel who met with us included the executive director, a former employee who performed financial and administrative services, and the accountant who provided accounting services to the subcontractor.
- We reviewed the correspondence between USC and HRSA that was provided to us and found no evidence that the costs questioned were retroactively approved.
- We provided sufficient information in the section titled “Research Involving Human Subjects” to explain that unapproved research involving human subjects occurred. Although the IRB’s chair provided administrative approval for the training grant, this approval was not in accordance with 45 CFR part 46, “Protection of Human Subjects.” The investigators did not separate the research component from the training initiative as recommended by the IRB chair. Therefore, the training fell under the IRB’s purview, and accordingly all costs associated with the training, contacting, recruiting, and enrolling of the human subjects are unallowable costs.
- We provided sufficient information to explain our determinations and calculations in the section titled “Unallowable Costs Claimed” and in the 33 explanatory notes contained in Appendices A and B. At the exit conference, we told USC officials that we would answer any questions and allow them to review our audit documentation to assist them in preparing a response to the report. Almost 5 months elapsed between the issuance of the draft report and our receipt of USC’s response. During this time, we did not receive any requests to explain our calculations or to make our audit documentation available.

If requested by HRSA officials, audit documentation will be made available to assist in resolving the audit findings. If needed, audit staff are also available to explain how we calculated our recommended disallowances.

APPENDICES

UNIVERSITY OF SOUTHERN CALIFORNIA
SCHEDULE OF COSTS CLAIMED AND RESULTS OF AUDIT
UNDER COOPERATIVE AGREEMENT NUMBER U69-HA-00040

Cost Category	Total Claimed	Recommended for Disallowance	Set Aside	Notes
Salaries/Wages	\$ 271,325	\$ 271,325	\$ -0-	1
Fringe Benefits	71,380	71,380	-0-	2
General Program	2,446	1,670	-0-	3
Office Expenses	15,830	3,782	-0-	4
Photocopy Expenses	3,040	3,040	-0-	5
Repairs/Maintenance	5,650	-0-	-0-	
Honorarium	8,040	8,040	-0-	6
Contract/Curriculum	25,000	25,000	-0-	7
Subcontractor	500,898	379,697	35,221	8
Professional Services	119,449	119,449	-0-	9
Travel	168,763	132,152	5,787	10
Postage	792	762	-0-	11
Indirect Costs	74,269	66,257	579	12
Total	\$1,266,882	\$1,082,554	\$41,587	

Note 1. Salaries and wages totaling \$271,325 are recommended for disallowance. USC had no documentation to support that the costs claimed were for work performed under the Federal program. OMB Circular A-21 required that salaries and wages be supported by activity reports, which reflect an after-the-fact distribution of activity. Activity reports should be signed by the employee, PI, or responsible official(s) using suitable means of verification that the work was performed. For professional personnel, the reports were required to be prepared at least every 6 months; for other personnel, the reports were required to be prepared at least monthly.

Our review disclosed instances where USC employees performed subcontractor work that was unrelated to the program, but their costs were charged to it. For example, we found employees worked on processing payroll, reviewing proposals for new programs, soliciting potential co-sponsors for an AIDS march, and facilitating townhall meetings in various States in conjunction with political action regarding HIV/AIDS.

In addition, our review disclosed that one employee had moved out of State in April 2000. The individual appeared to no longer be working on the program full-time. However, salary payments were made through June 2000 and claimed under the HRSA award.

Note 2. Fringe benefits totaling \$71,380 are recommended for disallowance. The fringe benefits charged to the program were calculated by multiplying the salaries and wages by USC's negotiated fringe benefits rate. The fringe benefits are related to the unallowable salaries and wages identified in Note 1.

Note 3. General program expenses totaling \$1,670 are recommended for disallowance. The recommended disallowance represents \$1,555 of costs that lacked the required prior approval from the awarding agency and \$115 in costs relating to unapproved research involving human subjects.

Note 4. Office expenses totaling \$3,782 are recommended for disallowance. The recommended disallowance represents the amount USC claimed in excess of HRSA's prior approval for office expense costs. HRSA approved \$1,050 for office expenses incurred before March 21, 2000. However, USC claimed \$4,832 for that period, or \$3,782 more than approved.

Note 5. Photocopy expenses totaling \$3,040 are recommended for disallowance. The recommended disallowance represents photocopying costs associated with home study guides sent to the research subjects. USC's IRB did not approve the research activity; therefore, the costs were unallowable.

Note 6. Honorarium costs totaling \$8,040 are recommended for disallowance. The recommended disallowance represents \$7,560 of costs associated with unapproved research and \$480 of costs that were not adequately supported.

Note 7. Curriculum development costs totaling \$25,000 are recommended for disallowance. USC did not obtain (1) HRSA's prior approval for subcontracting curriculum development to an outside vendor as required by Federal regulations and (2) written competitive bids for a purchase in excess of \$10,000 as required by USC purchasing policies. Further, USC lacked adequate documentation for the acceptance, inspection, and delivery of the product. We were unable to verify many of the deliverables, such as an indexed binder or a computer diskette. Also, a USC progress report provided that the curriculum was not the most ideal document, and the firm contracted to provide the curriculum had no real experience in developing curricula specific to HIV treatment education. The curriculum costs are not reasonable in accordance with OMB Circular A-21, since the costs incurred were not consistent with established institutional policies, and due prudence was not exercised by the individuals involved to ensure deliverables were satisfactory and accounted for.

Note 8. Subcontractor costs totaling \$379,697 are recommended for disallowance, and \$35,221 has been set aside for HRSA to determine allowability. See Appendix B and accompanying notes for description of subcontractor unallowable and set-aside costs.

Note 9. Professional service costs totaling \$119,449 are recommended for disallowance. The recommended disallowance consists of \$76,997 of consulting costs—for the period

September 1, 1999 through December 31, 1999—that were not approved by HRSA, \$36,452 in costs relating to unapproved research involving human subjects, and \$6,000 for public relations services that were not program-related.

The \$76,997 of consulting services did not have prior approval from HRSA for start-up costs. In addition, we found various problems with these costs, such as (1) the consultants were subcontractor employees and/or consultants who performed subcontractor activities unrelated to the program during the period September through December 1999; (2) most of the consultants endorsed their consulting fees over to the subcontractor for reimbursement of subcontractor wages or advances paid to the consultants; (3) consulting fees endorsed over to the subcontractor were greater than the wages/advances paid by the subcontractor; and (4) the consulting agreements contained a performance period for which individuals clearly did not work on the program as evidenced by an e-mail, dated November 18, 1999, informing USC that people needed to be hired to work on the program.

Consulting services totaling \$36,452 related to unapproved research involving human subjects. In addition, we found that consulting agreements had been entered into with a subcontractor employee, and a USC employee had “a controlling proprietary interest in or relationship with the consultant.” During the consulting period, the consultant was an employee of the subcontractor, and the USC employee was the chief executive officer and chairman of the board of the subcontractor.

Consulting services totaling \$6,000 were for public relations for the HIV University to be provided from April 15 to August 15, 2000. Based upon available documentation, the public relations services were primarily related to promoting the subcontractor and its activities.

Note 10. Travel costs totaling \$132,152 are recommended for disallowance, and \$5,787 has been set aside for HRSA to determine allowability.

The \$132,152 recommended disallowance consists of \$119,838 related to costs associated with services provided in conjunction with unapproved research involving human subjects, \$9,249 in costs that did not have prior approval by the awarding agency, \$1,242 in incorrect per diem amounts, \$1,250 in costs that were in excess of supporting documentation, and \$573 in travel costs that were not supported.

The \$5,787 of costs set aside represents travel costs that USC informed us it had supporting documentation for; however, as of the end of our fieldwork, USC had not yet provided the documentation. Therefore, we were unable to determine the allowability of these costs and, accordingly, we have set them aside.

Note 11. Postage costs totaling \$762 are recommended for disallowance. These costs were for services applicable to unapproved research activities.

Note 12. Indirect costs totaling \$66,257 are recommended for disallowance, and \$579 has been set aside for HRSA to determine allowability.

The \$66,257 recommended disallowance consists of \$62,856 associated with the unallowable modified total direct costs discussed above and \$3,401 in excess indirect costs resulting from a clerical error. Indirect costs charged to the program were calculated by multiplying the modified total direct costs by an indirect cost rate of 10 percent. Modified total direct costs include salaries and wages, fringe benefits, materials, supplies, services, travel, and subgrants and subcontracts up to the first \$25,000 of each subgrant or subcontract. The \$579 in set-aside indirect costs represents the indirect costs associated with the modified total direct costs set aside.

**SCHEDULE OF COSTS CLAIMED UNDER THE COST REIMBURSEMENT
CONSORTIUM AGREEMENT BETWEEN USC AND
THE SUBCONTRACTOR AND RESULTS OF AUDIT**

Invoice Category	Costs Claimed	Recommended for Disallowance	Set Aside	Notes
Project Director	\$ 20,234	\$ 20,234	\$ -0-	1
Temporary Staff	5,094	5,094	-0-	2
Financial Manager	14,000	-0-	14,000	3
Fringe Benefits	6,182	6,182	-0-	4
Postage & Delivery	1,003	724	-0-	5
Internship Site (MOU)	1,800	1,800	-0-	6
Per Diem Advisory	5,665	5,665	-0-	7
Equipment	67,117	27,602	-0-	8
Class I Per Diem	19,127	19,127	-0-	9
Audit	3,000	3,000	-0-	10
Consultants	27,321	24,059	3,262	11
Internet Service	1,406	1,129	277	12
Liability Insurance	1,667	129	1,538	13
Newsletter	90,664	90,664	-0-	14
Office Space	31,974	11,866	-0-	15
Training Space	73,600	73,600	-0-	16
Telephone	22,165	2,618	16,144	17
Videography	30,000	30,000	-0-	18
Web Page	50,820	45,150	-0-	19
International Community Treatment and Science Workshop (ICTSW)	28,019	11,014	-0-	20
Calculation Error	40	40	-0-	21
Total	\$500,898	\$379,697	\$35,221	

Note 1. Project director costs totaling \$20,234 are recommended for disallowance. These costs were not associated with a project director but were costs for wages paid to a temporary administrative assistant, a temporary logistic specialist, and a subcontractor employee who received consultant fees under the cooperative agreement and performed subcontractor activities under a different project. The subcontractor did not have supporting documentation for the wages charged to the program for these employees, such as timesheets and/or after-the-fact activity reports and certifications as required by OMB Circular A-122.

Note 2. Temporary staff costs totaling \$5,094 are recommended for disallowance. The costs were associated with the temporary logistic specialist referred to in note 1 above. The subcontractor did not have supporting documentation for the wages charged to the program, such as timesheets and monthly after-the-fact activity reports for the employee as required by OMB Circular A-122.

Note 3. The costs claimed for a financial manager totaling \$14,000 have been set aside for HRSA to determine allowability. The costs were for accounting services provided to the subcontractor for the months of July 2000 through January 2001 by an external accounting and technical services company. There was no agreement between the subcontractor and the company indicating the rate and basis used for payment. Under OMB Circular A-122, these types of costs are considered joint-type costs and should be prorated to all benefiting functions on a basis that accurately measures the benefits provided to each award or activity. The entire cost of these services was incorrectly claimed under this program.

Note 4. Fringe benefits totaling \$6,182 are recommended for disallowance. The subcontractor claimed fringe benefits in the second year of its agreement with USC. The fringe benefits were calculated by multiplying the subcontractor employee wages and fees paid for accounting services provided by an external company (see note 3) by a fringe benefit rate of 26.5 percent. The unallowable fringe benefits consist of the fringe benefits applicable to unallowable salaries and wages discussed in notes 1 and 2, and to nonexistent fringe benefits that were calculated based on costs associated with the external accounting and technical services company.

Note 5. Postage and delivery costs totaling \$724 are recommended for disallowance. The costs were primarily for the subcontractor's open house invitations and were not part of the subcontractor's scope of work under its agreement with USC.

Note 6. Internship site costs totaling \$1,800 are recommended for disallowance. The costs were associated with payments to a consultant for facility maintenance and data entry services. There was no consulting agreement for this individual. The services performed were not within the subcontractor's scope of work or its approved budget with USC.

Note 7. Per diem costs totaling \$5,665 relating to hotel accommodations for advisory board members, Durban-related activities, and the North American Treatment Forum are recommended for disallowance. The subcontractor did not have adequate documentation to support the hotel costs invoiced, and the Durban and North American Treatment Forum activities were not within the subcontractor's scope of work or approved budget and had no supporting documentation.

Note 8. Equipment costs totaling \$27,602 are recommended for disallowance. The recommended disallowance is due to one or more of the following reasons: (1) costs were incurred that required prior approval from HRSA or USC, (2) there was no supporting documentation, and (3) costs were invoiced that in were excess of actual costs.

Note 9. Per diem costs totaling \$19,127 are recommended for disallowance. The per diem costs were associated with meals and per diem costs provided in conjunction with unapproved research.

Note 10. Audit costs totaling \$3,000 are recommended for disallowance. The audit costs were associated with the audited financial statements and tax services provided to the subcontractor

for Calendar Year 1999. In accordance with the conditions of the cooperative agreement, costs incurred and charged to the program before March 21, 2000 required prior approval. These costs were incurred January 21, 2000, and did not have the required prior approval. In addition, these type of costs are joint-type costs and should be allocated among all of the subcontractor's benefiting programs. Based upon the subcontractor's general ledgers and audited financial statements for Calendar Year 1999, no costs were identified with the HRSA award.

Note 11. Consultant costs totaling \$24,059 are recommended for disallowance, and \$3,262 are set aside for HRSA's determination of allowability.

The \$24,059 recommended disallowance consists of \$19,502 in excess costs invoiced over actual costs, \$994 for costs that were not program related, and \$3,563 in consulting costs that were not within the subcontractor's scope of work or approved budget.

The \$3,262 of consultant costs set aside consists of \$2,752 in joint-type costs that should be allocated among all benefiting programs and activities and \$510 in costs that had insufficient supporting documentation to determine allowability.

Note 12. Internet costs totaling \$1,129 are recommended for disallowance, and \$277 has been set aside for HRSA to determine allowability.

The \$1,129 of internet costs were determined to be unallowable for one or both of the following reasons: invoiced costs were in excess of actual costs incurred, and costs lacked prior approval as required under the terms of the cooperative agreement.

The \$277 of costs set aside are joint-type costs that should be prorated among all of the subcontractor's benefiting programs and activities.

Note 13. Liability insurance costs totaling \$129 are recommended for disallowance, and \$1,538 is set aside for determination by the awarding agency.

The \$129 of unallowable costs consisted of costs claimed in excess of actual costs incurred and costs that were not covered by the performance period under the agreement with USC.

The \$1,538 of costs set aside were joint-type costs that should be prorated among all of the subcontractor's benefiting programs and activities.

Note 14. Newsletter expenses totaling \$90,664 are recommended for disallowance. The costs are unallowable for one or more of the following reasons: (1) newsletter expenses included costs that were not program related, such as grand opening invitations, subcontractor shirts, and copies of subcontractor's organizational brochures; (2) the newsletter did not meet the awarding agency's requirement because at least 65 percent of the content did not relate to HIV/AIDS treatment; (3) the number of newsletters printed and mailed was excessive and not supported by the subcontractor's statement of work; and (4) the subcontractor claimed more costs than allowed by the awarding agency.

Note 15. Office space expenses totaling \$11,866 are recommended for disallowance. The recommended disallowance consists of \$6,794 in rental costs that were not incurred by the subcontractor due to monthly rent being waived by the lessor for tenant improvements, and \$5,072 in related party costs included in the leasehold improvement allocation that did not have adequate support.

Note 16. Training space costs totaling \$73,600 are recommended for disallowance. The subcontractor was unable to identify actual costs incurred or provide adequate supporting documentation for these costs.

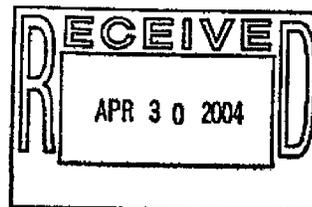
Note 17. Telephone expenses totaling \$2,618 are recommended for disallowance, and \$16,144 has been set aside for HRSA to determine allowability. The recommended disallowance consists of costs that were incurred before March 21, 2000, did not have the required prior approval, and could not be retroactively billed and charged to the program. The costs set aside are joint-type costs that should be prorated to all benefiting functions.

Note 18. Videography costs totaling \$30,000 are recommended for disallowance. The subcontractor used approved budget estimates for invoicing costs and was unable to identify actual videography costs that correlated to the amount invoiced.

Note 19. Web page costs totaling \$45,150 are recommended for disallowance. The unallowable amounts were due to one or more of the following reasons: (1) an excess amount was invoiced over actual costs identified, (2) costs were incurred before March 21, 2000 that did not have prior approval, (3) there were costs associated with activities not related to the program, and (4) there was inadequate documentation to support costs claimed.

Note 20. ICTSW costs totaling \$11,014 are recommended for disallowance. The costs were unallowable for one or both of the following reasons: (1) excess costs were invoiced over actual costs identified, and (2) there was inadequate documentation to support costs claimed.

Note 21. Unallowable costs totaling \$40 were due to an invoice calculation error that resulted in total costs being charged to the cooperative agreement that were in excess of the sum of the individual costs contained on the invoice.



April 29, 2004

Office of Compliance VIA OVERNIGHT MAIL

Lori A. Ahlstrand
Department of Health and Human Services
Office of Inspector General
50 United Nations Plaza, Room 171
San Francisco, California 94102

Re: Report Number A-09-02-01004

Ms. Ahlstrand:

I am the Senior Associate Vice President for the Office of Compliance and am submitting this response to the above report on behalf of the University of Southern California (USC). Thank you for granting USC an extension of time to respond to your draft report.

Before responding to the OIG's specific recommendations, let me first provide some background information regarding the research project under review.

This project was conducted pursuant to a cooperative agreement between USC and the sponsor, Health Resources and Services Administration (HRSA) [hereinafter, "HRSA Agreement"]. Cooperative agreements are similar to grants in that its principal function is to assist the recipient in carrying out a public purpose of support. The intent of the HRSA Agreement was to assist in building stronger community links to address the HIV prevention and health care needs of racial and ethnic minority communities. Specifically, the objective was to develop and evaluate a training center to train individuals to become peer treatment educators. The peer educators were expected to work in minority communities to increase awareness regarding issues related to HIV and AIDS.

Because this was a cooperative agreement, there was substantial involvement by HRSA in the project activities and therefore, close contact and coordination between HRSA and the university throughout the project. One of the co-Principal Investigators, Mr. Phill Wilson, had been identified by HRSA to lead the project because of his strong ties to the African-American and AIDS communities. At the time, he was serving as Executive Director of the African American Aids Policy and Training Institute (AAPTI), an organization established primarily to

assist with meeting the objectives of the HRSA Agreement. It is our understanding that HRSA suggested that AAAPTI partner with an educational institution on this project because AAAPTI was not incorporated as a tax-exempt entity and could not receive grant funds directly from HRSA. Mr. Wilson approached USC to serve in this regard and subsequently was hired by the university as a staff employee to serve as co-Principal Investigator on the HRSA Agreement. A USC faculty member was asked to serve as a co-Principal Investigator with Mr. Wilson.

Pursuant to the approval of HRSA, USC subcontracted a large portion of the statement of work on the project to AAAPTI. USC and HRSA required that certain measures be implemented to manage the conflict of interest as a result of Mr. Wilson's dual role with the subcontractor and USC, including that Mr. Wilson resign as Executive Director of AAAPTI.

At the inception of the project, the Co-Principal Investigators requested a claim of exemption from the federal regulations governing the protection of human subjects on the basis that the project did not involve human subjects research and was for training purposes only. The University Park Institutional Review Board (UPIRB) rejected the claim, but in an attempt to permit the training to begin, the UPIRB approved the training component of the protocol. The UPIRB did not permit the research aspects of the grant to proceed (e.g., recruitment and enrollment of human subjects, collection of data from peer educators, evaluation of the program, etc.) until further information was provided for UPIRB review and approval. The training component of the protocol was approved for one year only, at which time the Co-Principal Investigators were requested to submit an application for continuing review.

The Co-Principal Investigators were advised in writing that they could not proceed with the research component of the protocol without submitting further information to the UPIRB for review and approval. The requested documentation was not submitted to the UPIRB by the deadline and the university placed a freeze on all expenditures related to the protocol, pending resolution of the human subjects issues.

HRSA requested that USC partially lift the freeze on expenditures to permit payment of certain expenses relating to salary, rent and phone lines, among other things.

UPIRB and other university representatives met on several occasions with the Co-Principal Investigators to discuss a resolution of the issues involving protection of human subjects in research, including retaining an experienced researcher who could assist in addressing the IRB issues and developing the evaluation

component of the protocol. At that time, the UPIRB learned that AAAPTI had conducted aspects of the evaluation component of the protocol without UPIRB approval, although they were not completed. Written informed consent had been obtained from the subjects using a version of the UPIRB's template consent form, but the actual consent document and process for obtaining consent had not been approved by the UPIRB.

The University also learned at that time that Mr. Wilson had not adhered to the university's or HRSA's requirements for managing his conflict of interest.

Prior to its discovery of the human subjects and conflict of interest issues described above, USC attempted to terminate this project after its first year because of the difficulties it encountered in managing the personnel involved in the project. Specifically, it appeared to USC that Mr. Wilson, while a passionate advocate for HIV/AIDS-related issues, did not have an appreciation of the scientific and administrative requirements that had to be satisfied in order for the project to be successful.

As a result of HRSA's appeal, USC agreed to continue the project at that time and attempted to identify individuals at the university with more appropriate expertise to assume management of the HRSA Agreement. Before these issues could be fully addressed, HRSA suspended the project.

As the OIG acknowledged, the university has systems and controls in place to manage Federal funds. Those controls are evident, even with regard to this project. USC recognized that there were issues involved with the HRSA Agreement and was addressing them aggressively in partnership with HRSA, until the project was suspended. At the time of suspension, USC already had: (1) instituted and maintained a freeze on expenditures, (2) identified another investigator to assume the responsibilities of the project; and (3) commenced an independent and comprehensive financial audit of the subcontractor, AAAPTI.

Notwithstanding the above, mistakes were made in connection with this project. Accordingly, the university has used this opportunity to re-evaluate its sponsored projects management system and to further improve its processes in order to avoid these anomalies in the future. Those improvements are discussed in further detail below.

The results of this project are particularly unfortunate because USC is nationally recognized for its community outreach programs, including those serving the HIV/AIDS population in Los Angeles. The university otherwise has enjoyed a successful research partnership with HRSA.

The following responds to each of the OIG recommendations:

OIG Recommendations #1 and #2

- Strengthen its cooperative agreement implementation process to include the full support of the university community by ensuring that the proper organizational infrastructure and managerial, professional, and research expertise are available for meeting the objectives of future federally funded programs.
- Establish independent oversight of investigators who need increased supervision.

USC Response:

The university concurs and already has taken substantial steps to address both recommendations.

The university has a longstanding requirement that research proposals submitted on behalf of the university must be approved in writing by the senior administration of the particular school or unit that intends to engage in the research (e.g., Chairperson, Division Chief, Dean). This method of accountability at the school or unit level has been effective in ensuring that there are appropriate resources and expertise necessary to conduct the research at issue. Even in this case, the Dean of the relevant unit recognized after the first year of the project that the HRSA Agreement would be more appropriate within a university unit that had particular expertise in the areas of HIV/AIDS education.

The university also continues to provide a variety of resources to assist university investigators, research staff and administrators and to provide additional oversight when needed. These resources include the following:

- **Sponsored Projects Manual:** This manual was revised in February 2001, and describes in detail the university's process for managing sponsored projects from proposal through closing. The manual also provides contact information and other resources available to support university investigators and administrators.
- **The Proposal Approval Record (PAR):** The PAR is used as a routing endorsement sheet for each proposal. It provides basic information about the proposal and serves as a checklist for investigators to ensure that they have complied with necessary regulatory and university requirements. The investigator's Chair and Dean must sign the PAR, indicating that the

respective school approves of the proposal submission. The Department of Contracts and Grants will not submit a proposal until the PAR has been provided.

The university continues to revise and improve the PAR to ensure that it remains current with the changing regulatory environment and to educate investigators about research compliance issues. As an example, the PAR was revised to address several issues identified as a result of the HRSA Agreement. Those revisions are discussed below in further detail.

- **Executive Research Compliance Committee:** This committee is comprised of representatives from the university research community at the University Park and Health Sciences Campuses. It is co-chaired by the Vice Provost for Research and the Vice President for Health Affairs and reports directly to the Senior Vice President for Medical Care. Its members review and provide input on university-wide research compliance policy issues, including the development and implementation of education, policies and procedures. The committee also oversees the compliance efforts of the university's research regulatory review committees, such as the Institutional Review Boards, the Institutional Animal Care and Use Committee and others. This committee provides a forum for researchers and administrators to identify and discuss research policy issues.
- **Audit Services research compliance methodology:** The Offices of Compliance and Audit Services jointly developed a detailed audit methodology, which is utilized by the university's internal audit department during the course of their business reviews of schools or units that conduct research. The auditor reviews unit controls and samples documentation to determine the level of compliance with university policy and federal regulations regarding research administration. Each unit must respond to the findings in the audit and describe its corrective action plan. Audit Services conducts a subsequent audit of each unit to ensure that the findings identified in the review have been corrected. The research audit tool not only assists the university in identifying investigators or departments that may require additional oversight, but it also serves an educational function in that audited departments and units are reminded of the resources on campus that are available to assist them with research compliance and operations. Further, the audit tool assists the university in determining what resources are required at the school and unit levels to ensure that they are meeting the requirements of our research sponsors.

- **Human Subjects Director:** The university recently hired an Executive Director for the newly created USC Office for Protection of Research Subjects. This individual is responsible for designing and directing the development of a human subjects research protection program, which includes coordinating, evaluating and overseeing the operations, policies and procedures of the Institutional Review Boards at the University Park and Health Sciences Campuses. A critical aspect of this position is educating our investigators and research staff regarding human subjects protection issues.
- **Education Programs:** Since the commencement of the HRSA Agreement, the university has established a number of formal and informal educational programs for investigators and staff, including the following:
 - **Human Subjects Education Program** – The university has developed a comprehensive program for investigators and staff regarding the regulations and university policies for protecting human subjects in research. As of September 2000, the program has been required for all key personnel participating in NIH-funded human subjects research. Our program includes a case study that addresses the distinctions between training and research to demonstrate when IRB approval is required. The case study is based on the issues identified as a result of the HRSA Agreement. The university required that Mr. Wilson attend this program.
 - **Grants Management Education Program** – USC recently introduced a grants management education program entitled, “Preserving the Public Trust in Research: A USC Partnership to Promote Research Integrity.” The program consists of two courses: (1) A course primarily designed to address fiscal and administrative issues associated with sponsored projects from project proposal through closeout, which is presented via live lectures and case studies; and (2) A course that emphasizes research integrity issues, such as conflict of interest, scientific misconduct, peer review, data management and mentoring, which is available online. The program includes a case study that addresses the distinctions between training and research to demonstrate when IRB approval is required. The case study is based on the issues identified as a result of the HRSA Agreement. Beginning July 1, the program will be mandatory for investigators and research administrators.

- **Research Administrators Forum – The Research Administrators Forum meets several times per year to discuss current research administration issues. All university research administrators are invited to attend. The Forum has been meeting for the past two years and has been well received. Approximately 100-150 administrators attend on a regular basis. In addition, administrators who may require additional supervision are specifically invited and encouraged to attend.**
- **Senior Business Officers Education - Last year, the university began offering a comprehensive education program for its Senior Business Officers. These individuals generally serve as chief financial officers for their respective schools or units. The education program includes presentations on ethics and research compliance, as well as financial and administrative best practices, among other things.**

OIG Recommendation #3

Ensure that university offices involved with the approval of and funding for research activities work together to clarify guidelines and improve communications related to programmatic decisions and funding actions.

USC Response:

The university concurs and already has implemented improvements in its research administration process to address this recommendation.

Although there is frequent communication between the offices that administer the university's research activities, USC used this opportunity to further improve and formalize some of these processes. Those improvements include the following:

- **The Department of Contracts and Grants requires all of its staff to complete USC's human subjects education program so that the staff understand and can identify potential human subjects research issues. In addition, the department expanded and formalized its existing internal procedures to confirm that IRB approval must be obtained before investigators conducting human subjects research can obtain access to their funds.**

- The Department of Contracts and Grants and the University Park Institutional Review Board formalized a process to improve their reporting and communications.
- The university hired an Executive Director for the newly established Office for Protection of Research Subjects, who coordinates education, communication and policy making across relevant USC departments in the area of human subjects research.
- The education programs described above require coordination between the research administration departments, which provides additional opportunities for those representatives to meet and discuss issues.

As a result of these and other activities, we continue to improve our communications across those departments responsible for pre-award and post-award administration.

OIG Recommendation #4

Strengthen procedures for reviewing, identifying and resolving potential and actual conflicts of interest.

USC Response:

The university concurs and already has implemented improvements in its research administration process to address this recommendation.

The university recently revised its conflict of interest policies relating to research and general university business practices. The conflict of interest in research policy incorporates guidance provided by the Association of American Universities (AAU) and the Association of American Medical Colleges (AAMC). For example, the university adopted the recommendations by the AAU and AAMC that the policy should apply to all research, regardless of funding.

The PAR, which already included a reference to the university's conflict of interest in research policy, was further revised to incorporate additional information to assist investigators in identifying whether they have an actual or perceived conflict of interest that requires disclosure.

Pursuant to our policy, the university's Disclosure Review Committee is charged with reviewing investigator disclosures of actual and perceived conflicts of interest in research and determining how such conflicts should be managed.

In addition, both courses of the university's grants management education program, which becomes mandatory on July 1, 2004, address conflicts of interest in research in great detail. One of the courses includes an entire chapter on this subject. Further, the Office of Compliance and the Vice Provost for Research regularly make presentations to university faculty and staff about research compliance issues, including conflicts of interest in research.

OIG Recommendation #5

Refund to HRSA \$1,082,554 in unallowable reimbursed and unreimbursed costs.

USC Response:

The university understands that mistakes were made with respect to this project by all parties involved. With that said, however, we disagree with this recommendation and request that HRSA provide the university with an opportunity to discuss this matter further for the following reasons.

Independent Subcontractor Audit

The OIG disallowed almost all of the charges paid to the subcontractor, AAAPTI. While the university agrees that certain costs are not allowable, we disagree with the OIG's calculations.

The university engaged Pricewaterhouse Coopers (PwC) to conduct a comprehensive six-month audit of the subcontractor, AAAPTI, immediately following HRSA's diagnostic site visit. Because the timing of the PwC audit occurred soon after the site visit and the subsequent project suspension, the audit team had access to additional records and personnel (such as AAAPTI's accountant) that were not available to the OIG team when they conducted their review over one year later. Also, the OIG's onsite review lasted less than two days. There is no reference whatsoever to the university's audit in the OIG's draft report.

The OIG review team indicated that they did not utilize the results of the university audit because it included a review of claimed expenses (i.e., expenses that had been charged by the subcontractor, but not yet paid). This is not a reason to discount the report in its entirety. It simply means that the university's audit includes more information than what is required for purposes of the OIG review. Accordingly, we believe that the university's audit is a more accurate reflection of

allowable expenses and, at minimum, should be the starting point for a discussion about appropriate expenses charged by AAAPTJ.

Retroactive Approval of Initial Costs

The OIG disallowed certain initial costs of the HRSA Agreement because USC did not obtain HRSA's prior approval. However, HRSA gave retroactive approval to these costs soon after they were incurred. The university contends that it is unreasonable to disallow costs that subsequently were approved by the sponsor.

Human Subjects Review

The OIG also disallows certain charges on the grounds that they related to unapproved research involving human subjects. First, it is not clear how the OIG calculated these claims. Second, while the university does not condone the actions taken by the investigators, there was some attempt to obtain written informed consent from the subjects, although the consent document and the process for obtaining consent were not approved by the IRB. Furthermore, the university was attempting to address this matter when the project was suspended. Accordingly, the university would like to understand how the OIG came to its calculations to disallow certain expenses based on "unapproved research."

As a general matter, it is difficult for USC to respond with specificity to many of the recommendations for disallowance of expenses because there is insufficient information provided in the OIG's draft report as to how such calculations or disallowance determinations were made. We would appreciate an opportunity to review the documentation or other materials upon which the OIG has relied to recommend for disallowance the expenses set forth in the draft report. We also would appreciate the opportunity to discuss this matter further with HRSA since the sponsor was actively involved with this project and aware of certain expenses associated with the project.

OIG Recommendation #6

Work with HRSA to resolve the allowability of \$41,587 in costs that [OIG] set aside.

USC Response:

The University looks forward to working with HRSA to resolve this matter.

The HRSA Agreement was an unusual project for many reasons and is not a reflection of the research or administrative capabilities of the university. While mistakes were made, we believe that the university's checks and balances in its grants management system were effective in identifying the issues associated with this project in its early stages. Indeed, USC already had been addressing the problems described in the OIG draft report prior to HRSA's suspension or the OIG review. Nevertheless, the HRSA Agreement also identified certain weaknesses, which subsequently have been corrected, and as a result, we have further enhanced our grants management system so as to avoid similar issues in the future.

Please do not hesitate to contact me at (213) 740-8258 if you have any further questions.

Sincerely,



Laura L. LaCorte
Senior Associate Vice President